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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/708,808	03/26/2004	John R. Mitchell	04M1700	2807
24234	7590	12/08/2005	EXAMINER	
SIMMONS, PERRINE, ALBRIGHT & ELLWOOD, P.L.C. THIRD FLOOR TOWER PLACE 22 SOUTH LINN STREET IOWA CITY, IA 52240			WIEKER, AMANDA FLYNN	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 12/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

6

Office Action Summary

Application No.

10/708,808

Applicant(s)

MITCHELL, JOHN R.

Examiner

Amanda F. Wieker

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 20 is/are rejected.
- 7) ☒ Claim(s) 19, 21 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/14/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required if the application is allowed.
2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the subject matter of claims 4 and 17 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Art Unit: 3743

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification lacks antecedent basis for the subject matter of claim 4.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The second/left end's shoe and/or shoe engaging plate and/or adjustment means are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Because the device cannot function without BOTH feet attached at the left and right ends of the device, the claims are not enabled to allow one skilled in the art to make and/or use the invention with only one (left or right) foot secured to the splint.

Claims 16-19 are objected to as being dependant on a rejected claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 4,088,129 to DiGiulio.

DiGiulio discloses a system for maintaining a child's feet in a predetermined therapeutic arrangement, the system comprising:

- a splint comprising:

- a rigid elongated member (2) comprising a left end and a right end;

- a right shoe engaging plate (90) adjustably coupled to said elongated member;

- a right end adjustment mechanism (see Figure 2) disposed between said right shoe engaging plate (90) and said elongated member (2), said right end adjustment mechanism for making angular adjustments (see col. 7);

- a quick release mechanism (80) coupled to said right shoe engaging plate (90); and,

- a recess (98) integrally formed in a sole portion of a shoe (through integral connection via adhesive or rivets; col. 8, lines 13-18), wherein said recess (98) is configured to receive and selectively latch therein said quick release mechanism (element 94 of 80).

DiGiulio discloses each and every structural element of the system set forth in claim 2. DiGiulio discloses a sole that is a single piece of material (100), but DiGiulio is silent as to the method of making the sole. The claimed phrase "single piece of molded material" is being treated as a product by process limitation; that is, that the sole is made by molding.

As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

Thus, even though DiGiulio is silent as to the process used to make the sole, it appears that the product in DiGiulio would be the same or similar as that claimed, especially since both applicant's product and the prior art product disclose soles to be connected to a splint.

The system includes a second shoe coupled to a second end of the adjustable splint assembly.

DiGiulio anticipates a method of treating a patient's club feet at a predetermined angular orientation and separation with respect to each other, the method comprising the steps of:

providing a first shoe (left) with a sole having structure formed integrally therein (through integral connection via adhesive or rivets; col. 8, lines 13-18), configured to couple with a first latching mechanism (94 of 80), without using an elongated threaded member extending into said sole,

inserting a patient's foot into said first shoe;

providing a second shoe (right) with a sole having structure formed integrally therein (through integral connection via adhesive or rivets; col. 8, lines 13-18), configured to couple with a first latching mechanism (94 of 80), without using an elongated threaded member extending into said sole;

providing an elongated member (2) having an adjustable length;

coupling said first shoe to a first end of said elongated member; and,

coupling said second shoe to a second end of said elongated member.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3743

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiGiulio in view of U.S. Patent Number 5,483,757 to Frykberg.

DiGiulio discloses the previously described system for maintaining a child's feet in a predetermined therapeutic arrangement. DiGiulio specifies that any type of shoe can be used with the system, but does not specify the presence of an orifice on the side of the heel.

Frykberg discloses a shoe for maintaining a patient's foot in a predetermined therapeutic position. Frykberg discloses an orifice (56) on each side of the heel (that extends across the back of the heel, to both sides of the heel) to minimize pressure on the heel, and which is fully capable of permitting viewing of the patient's foot.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the system for maintaining a child's feet in a predetermined therapeutic arrangement disclosed by DiGiulio, wherein the shoe includes an orifice on each side of the heel, as taught by Frykberg, to minimize pressure on the heel, and which is fully capable of permitting viewing of the patient's foot.

10. Claims 7-9, 11 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiGiulio in view of U.S. Patent Number 6,173,511 to Perrault.

DiGiulio discloses the previously described system for maintaining a child's feet in a predetermined therapeutic arrangement. DiGiulio specifies that any type of shoe can be used with the system, but does not specify the insole of the shoe to include a single piece insole member.

Perrault discloses a shoe for maintaining a user's foot in a predetermined therapeutic position. Perrault discloses a one-piece insole member to support the foot, while taking up a limited amount of space within the shoe. The insole has a flat foot side, and a pair of opposing insole side walls and an insole heel support section. Absence of material (at 22) in the heel support section permits visual inspection from both sides (through 22, to left and right) of a patient's heel.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the system for maintaining a child's feet in a predetermined therapeutic arrangement as disclosed by DiGiulio, wherein the shoe includes a one-piece insole, as taught by Perrault, to support the foot while taking up a limited amount of space within the shoe.

11. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiGiulio in view of Perrault and in view of U.S. Patent Number 2,585,342 to Morgan.

DiGiulio in view of Perrault disclose the previously described system for maintaining a child's feet in a predetermined therapeutic arrangement. DiGiulio specifies that the length of the elongated splint be adjustable, but does not specify that the splint include a plurality of bars joined together by bolts.

Morgan discloses a system for maintaining a child's feet in a predetermined therapeutic arrangement, wherein the system comprises a plurality of bars (10, 12) joined together by bolts to allow precise adjustment of the splint assembly. The system of bars and bolts comprise a shoe separation setting device with first (14 left) and second (14 right) setscrews.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the system for maintaining a child's feet in a predetermined therapeutic

Art Unit: 3743

arrangement disclosed by DiGiulio in view of Perrault, wherein the system includes a plurality of bars joined by bolts, as taught by Morgan, to allow precise adjustment of the splint assembly.

Allowable Subject Matter

12. Claims 19 and 21-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda F. Wieker whose telephone number is 571-272-4794. The examiner can normally be reached on Monday-Thursday, 7:30 - 5:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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